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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/023,182
Filing Date: December 17, 2001
Appellant(s): STOCKERT ET AL.

NORMAN D. HANSON
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 07, 2006 appealing from the Office action mailed November 23, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

Appellant asserts that the Advisory Action of October 06, 2005 does not indicate if the Amendment was enter; however, as rejections were withdrawn, it appears that it was.

This is not correct. The amendment after final rejection filed on August 03, 2005 has been entered, as shown in the PTOL-303 of the Advisory action of October 06, 2005 (see item # 7 of the PTOL-303).

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Greenspan et al, "Defining epitopes: It is not as easy as it seems", Nature Biotechnology, vol. 7, (October 1999), pp. 936-937.

Herbert et al, eds, The Dictionary of Immunology, 4th edition, 1995, Academic Press, San Diego, CA, p.58

Kirkin et al, "Melanoma-associated antigens recognized by cytotoxic T lymphocytes". APMIS, (1998), vol.106, pp. 665-679

Stites et al, eds, Medical Immunology, 9th edition, 1997, Appleton & Lange, Stamford, Connecticut, p. 130.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 34-37, 40 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claim 32 is drawn to an isolated protein consisting of an immunoreactive portion of a protein encoded by an isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO:1, wherein said immunoreactive protion is processed by a cell to form a peptide which complexes to an MHC molecule and provides a T cell response.

Claims 34-35 are drawn to the isolated protein of claim 32, wherein said MHC molecule is a Class II molecule (claim 34), or a Class I molecule (claim 35).

Claims 36-37 are drawn to a composition comprising the isolated protein of claim 32, and an adjuvant (claim 36), wherein said adjuvant is a saponin, GM-CSF, or an interleukin (claim 37).

Claim 40 is drawn to the isolated protein of claim 32, wherein said immunoreactive portion of the protein is an amino acid sequence of a tumor rejection antigen.

The specification discloses that the peptides of SEQ ID NO:4, 5, and 6 from the NY-ESO-1 polypeptide encoded by SEQ ID NO:1 could elicit a T cell response, wherein SEQ ID NO:4, 5, 6 consists of 11, 9, and 9 amino acids in length, respectively, and share a core peptide sequence of SLLMWIT (Example 12, pages 24-25). The specification discloses several peptides from SEQ ID NO:1 that have HLA binding motifs (Example 13, on pages 25-26). The specification discloses that melanoma patients contain antibodies in serum to the protein NY-ESO-1, encoded by SEQ ID NO:1 (p.15, first paragraph).

It is noted that SEQ ID NO:1 is a cDNA fragment of 752 nucleotides in length, encoding a fragment of the NY-ESO-1 protein, which fragment is relatively large and thus would contain numerous peptide epitopes. In view of a lack of a definition of "immunoreactive portion", and in view of the large size of the protein fragment NY-ESO-1 encoded by SEQ ID NO:1 of 752 nucleotides in length, **the claims encompass a genus of** "immunoreactive peptides" derived from the protein encoded by SEQ ID NO:1, i.e., **any linear or conformational T cell epitopes** of the protein encoded by SEQ ID NO:1, wherein said peptides do not have to share the same common structure SLLMWIT of the 9-11 amino acids peptide SEQ ID NO:4, 5 and 6.

Although the recited several peptides from SEQ ID NO:1 have HLA binding motifs, and are expected to bind to HLA molecule, one cannot predict that these peptides also elicit sufficient T cell response. It is well known in the art that not any peptides of an amino acid sequence could bind to an MHC molecule and provide a T cell response. Stites et al, 1997 (Medical Immunology, 9th ed, Appleton & Lange, Stamford, Connecticut, page 130) teach that T cell receptors recognize the ligands comprising peptide antigens that are bound to MHC molecules, and that individual T cells respond only to a specific combination of antigen and MHC. In other words, peptides that are expected to bind to MHC molecules, such as those disclosed in the specification are not necessarily ligands of T cell receptors, wherein said ligands provide a T cell response, because T cell receptors have to recognize a specific combination of antigen and MHC. This is further supported by the teaching of Kirkin et al, 1998, (APMIS, 106: 665-679), which reviews several melanoma associated antigen, and concludes that only few peptides from melanoma associated antigens have been so far identified as being recognized by specific CTLs, and that some Melan-A/MART-1 peptides although having high affinity for HLA-A2.1 antigen

do not induce the generation of melanoma specific CTLs in vitro (p.670, second column). Thus **the specification does not provide adequate examples of the claimed T cell epitopes that invokes a T cell response, by providing examples of peptides that are expected to bind to MHC molecules.**

Further, although the specification discloses three peptides SEQ ID NOs:4, 5 and 6, which share with each other the common T cell epitope SLLMWIT, one cannot predict which fragments of the protein encoded by SEQ ID NO:1, other than SEQ ID NO:4, 5 and 6, also contain T cell epitopes, in view of the above teaching of Stites et al, and Kirkin et al, and further in view of the following teaching. It is noted that peptide epitopes of T cells could be linear or conformational to fit into the three dimensional structure of the T cell receptor, and that each peptide epitope of individual set of T cells is structurally and/or conformationally different from each other, because of difference in the structure of individual set of T cell receptors. However, there is no teaching in the specification of whether or not the claimed epitopes are linear or comprise 3-dimensional structures, nor the 3-dimensional structure of the claimed peptide epitopes is disclosed. Herbert et al, 1995 (The Dictionary of Immunology, Academic Press, 4th edition, p.58) define epitopes as the region on an antigen molecule to which antibody or the T cell receptor binds specifically wherein the 3-dimensional structure of the protein molecule may be essential for antibody binding. However, the specification fails to disclose sufficient guidance and objective evidence as to the linear and or three-dimensional conformation of the polypeptide fragments which constitute epitopes recognized by T cell receptors the claimed invention. Moreover, as evidenced by Greenspan et al, 1999, (Nature Biotechnology 7:936-937), defining epitopes is not as easy as it seems. Even when the epitope is defined, in terms of the spatial

organization of residues making contact with ligand, then a structural characterization of the molecular interface for binding is necessary to define the boundaries of the epitope (page 937, 2nd column). Thus, in view of the above teaching of Stites et al, Kirkin et al, Herbert et al, and Greenspan et al, one cannot predict which fragments of the protein encoded by SEQ ID NO:1, other than SEQ ID NO:4, 5 and 6, also contain T cell epitopes.The specification however has not identified which amino acid fragments of the protein encoded by SEQ ID NO:1 are critical or essential characteristics of the claimed linear and conformational T cell epitopes, other than the linear peptides of SEQ ID NO:4, 5, 6 that elicit CTL response.

Further, there is **no known common structure between the claimed immunoreactive portions,** which encompass linear or conformational T cell peptide epitopes**, and the peptides SEQ ID NO: 4, 5, or 6**, because the encompassed T cell epitopes could be any immunoreactive fragments, i.e. any T cell epitopes, of the protein encoded by SEQ ID NO:1, and do not necessarily have to have the same common structure of SEQ ID NO:4, 5, 6. In view of such a lack of a known common structure, there **is no correlation between structure of the encompassed genus of T cell epitopes and the function of inducing T cell response**. In addition, because there is no known common structure between SEQ ID NO: 4, 5, or 6 and the encompassed T cell epitopes, the disclosed peptides **SEQ ID NOs:4, 5, 6 are not representative species**.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli

Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that □[a] written description of an invention involving a chemical genus, like a description of a chemical species, □requires a precise definition, such as by structure, formula, [or] chemical name,□ of the claimed subject matter sufficient to distinguish it from other materials.□ Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the

genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here.

Thus, the instant specification may provide an adequate written description of the claimed immunoreactive portion, per Lilly by structurally describing a representative number of immunoreactive portions, or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the immunoreactive portion in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide sufficient structure or common structure, other than the peptides SEQ ID NO: 4, 5, and 6, to support the broad breath of the claimed genus. Nor is there any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses the peptides of SEQ ID NO:4, 5, and 6, this does not provide a description of the claimed immunoreactive portions that would satisfy the standard set out in Enzo.

The specification also fails to describe the immunoreactive portions by the test set out in Lilly. The specification describes only the linear peptides of SEQ ID NO:4, 5, and 6 that induce T cell response. Therefore, it necessarily fails to describe a "representative number" of such species, which includes unknown conformational T and B cell epitopes, in addition to linear B and T cell epitopes of unknown and diverse structure, because each epitope has a unique structure, whether it is linear or conformational. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The specification does not provide an adequate written description of the claimed genus of immunoreactive portions that is required to practice the claimed invention. Thus, the specification does not meet the 112, first paragraph written description requirement, and one of skill in the art would reasonably conclude that Appellant did not have possession of the claimed genus of immunoreactive portions at the time the invention was made.

(10) Response to Argument

A. Appellant argues that it seems that the Examiner has issues with insufficient number of immunoreactive peptides are disclosed.

The Examiner takes note that this is a misrepresentation of the Examiner position.

The issue is not that insufficient number of immunoreactive peptides are disclosed, but rather the issue is:

1) The three disclosed peptides **SEQ ID NO:4, 5, 6**, that elicit T cell response, are **not representative species**, because there is **no known common structure** between the three disclosed 9-11 amino acids peptides SEQ ID NO:4, 5, 6 and the claimed genus of immunoreactive peptides, i.e. **any** linear and conformational T cell epitopes, of the protein encoded by SEQ ID NO:1.

2) The **disclosed 20 peptides that are expected to bind to MHC molecules are not representative species**, because at the time the invention was made, one cannot predict that any of these peptides also has the ability to elicit sufficient T cell response.

Appellant argues that there are over 20 disclosed peptides at page 26, that do share a common structure; that is they must consist of an amino acid sequence found in SEQ ID NO:1, and they must be of the proper size to bind to MHC molecules. Appellant argues that with respect to common structure, although the structure needed to bind to particular MHC molecule does vary depending on the MHC molecule, however, Appellant discloses this rule, as shown in the cited references by Parker et all, and D'Amaro et al. Appellant argues that all one need to do is to look up a motif, for example, HLA-B8 and one would find out the size of the peptides, which binds to HLA-B8 and what amino acids are required, and at what positions. Appellant argues that although Appellant does not disagree that binding to an MHC molecule does not

guarantee provocation of a T cell response, however, the examples clearly teach how to determine if a T cell response is generated.

This is not found to be persuasive.

Although all the claimed immunoreactive portions share the structural requirement of having to have an amino acid sequence encoded by SEQ ID NO:1, i.e. they have to be fragments of the amino acid sequence encoded by SEQ ID NO:1, there is no disclosed common structure, because the claimed genus of immmunoreactive portions, i.e, a genus of T cell epitopes, encompass any immunoreactive fragments, i.e. **any T cell epitopes**, of the protein encoded by SEQ ID NO:1, and do not necessarily have to have the same common structure of the T cell epitopes SEQ ID NO:4, 5, 6, and because each epitope has a unique structure, whether it is linear or conformational. This is clearly shown, for example, by the peptides consisting of amino acids 80-88, 94-102, and 157-170 of NY-ESO-1, disclosed **after** the invention was made, as submitted by Appellant in the response of 04/01/05, and referred to on page 4, second paragraph of the instant brief.

Further, although the specification discloses 20 peptides on the table on page 27, said peptides are only disclosed as having the motifs that are expected to bind to MHC molecules. However, one cannot predict which peptides, that are expected to bind to MHC molecules, also could elicit T cell response, because of the following teaching of Stites et al, Kirkin et al, Hebert et al, and Greenspan et al. It is well known in the art that not any peptides of an amino acid sequence could bind to an MHC molecule and provide a T cell response. Stites et al, 1997 (Medical Immunology, 9th ed, Appleton & Lange, Stamford, Connecticut, page 130) teach that T cell receptors recognize the ligands comprising peptide antigens that are bound to MHC

molecules, and that individual T cells respond only to a specific combination of antigen and MHC. In other words, peptides that are expected to bind to MHC molecules, such as those disclosed in the specification are not necessarily ligands of T cell receptors, wherein said ligands provide a T cell response, because T cell receptors have to recognize a specific combination of antigen and MHC. This is further supported by the teaching of Kirkin et al, 1998, (APMIS, 106: 665-679), which reviews several melanoma associated antigen, and concludes that only few peptides from melanoma associated antigens have been so far identified as being recognized by specific CTLs, and that some Melan-A/MART-1 peptides although having high affinity for HLA-A2.1 antigen do not induce the generation of melanoma specific CTLs in vitro (p.670, second column). It is noted that peptide epitopes of T cells could be linear or conformational to fit into the three dimensional structure of the T cell receptor, and that each peptide epitope of individual set of T cells is structurally and/or conformationally different from each other, because of difference in the structure of individual set of T cell receptors. However, there is no teaching in the specification of whether or not the claimed epitopes are linear or comprise 3-dimensional structures, nor the 3-dimensional structure of the claimed peptide epitopes is disclosed. Herbert et al, 1995 (The Dictionary of Immunology, Academic Press, 4th edition, p.58) define epitopes as the region on an antigen molecule to which antibody or the T cell receptor binds specifically wherein the 3-dimensional structure of the protein molecule may be essential for antibody binding. However, the specification fails to disclose sufficient guidance and objective evidence as to the linear and or three-dimensional conformation of the polypeptide fragments which constitute epitopes recognized by T cell receptors the claimed invention. Moreover, as evidenced by Greenspan et al, 1999, (Nature Biotechnology 7:936-937), defining

epitopes is not as easy as it seems. Even when the epitope is defined, in terms of the spatial organization of residues making contact with ligand, then a structural characterization of the molecular interface for binding is necessary to define the boundaries of the epitope (page 937, 2nd column). Thus, in view of the above teaching of Stites et al, Kirkin et al, Herbert et al, and Greenspan et al, one cannot predict which fragments of the protein encoded by SEQ ID NO:1, other than SEQ ID NO:4, 5 and 6, also contain T cell epitopes.The specification however does not identify which amino acid fragments of the protein encoded by SEQ ID NO:1 are critical or essential characteristics of the claimed linear and conformational T cell epitopes, other than the linear peptides of SEQ ID NO:4, 5, 6 that elicit CTL response. Thus, in view of such unpredictability, there is no correlation between structure of the disclosed 20 peptides that are expected to bind to MHC molecules and the function of eliciting T cell response.

Further, although the specification discloses examples of how to screen for peptides that have T cell response, Appellant is reminded that the 112, first paragraph, written description requires that Appellant had possession of the claimed genus of peptides that elicit T cell response at the time the invention was made. Teaching how to screen for a peptide that has T cell response is not an adequate description of the structure of the claimed genus of immunoreactive peptides. It is noted that "**adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it** (emphasis added). The nucleic acid itself is required". See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that **a generic statement which defines a genus of nucleic acids by only their functional activity**

does not provide an adequate written description of the genus (emphasis added). The court indicated that "while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus". At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Appellant argues that although the specification does not define "immunoreactive portion", no case precedent holds that the breadth of a claim de facto means that it fails to satisfy the written description requirement.

The Examiner takes note that although lacking definition does not always means that it fails to satisfy the written description requirement, however, in the instant application, in view of a lack of definition of "immunoreactive portion", the claimed "immunoreactive portion" encompasses a genus of linear and conformational T cell epitopes of the protein encoded by SEQ ID NO:1, and in view that the disclosed three T cell epitoptes, peptides SEQ ID Nos: 4, 5 and 6, and the disclosed 20 peptides that are only expected to bind to MHC molecules are not representative species, supra, and further in view that there are no common structure among the disclosed three T cell epitope peptides and the encompassed T cell epitopes, supra, the claims and the specification do not meet the standards as shown in the examples of Lilly or Enzo. Thus the claims and the specification do not meet the 112 first paragraph, written description requirement.

B. Appellant argues that the discussion of B cell response is completely out of order, because claim 32 has been amended to limit to T cell response.

The Examiner apologizes for any inconvenience caused by inadvertently not to remove the discussion on B cell response in the final rejection.

C. Appellant argues that Lilly per se does not support the Examiner position. Appellant argues that further development of the law since Lilly, and the Interim Written Description Guidelines clearly show that the Examiner's position is incorrect. Appellant recites Example 14 of the written description, in which a claim, drawn to a protein of SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B, meets the written description requirement, even though only one specific species is identified, in view of the disclosure of an assay for determining if the catalytic activity is present. Appellant argues that the claim in Example 14 is generic, and no structural information relating to active sites is disclosed, and that only a single embodiment is shown. Appellant argues that the specification satisfies every thing set forth in the Example 14. Appellant argues that every claimed molecule must have a sequence found in the protein encoded by SEQ ID NO:1, and no variations are possible. Appellant argues that processes for truncating full length proteins are well known. Appellant argues that the specification discloses what amino acids, and what spacing in between these is necessary for binding to a particular MHC molecules. Appellant argues that the specification teaches assays for determining if the protein is in fact processed to a peptide which stimulates T cells.

This is not found to be persuasive. Example 14 is not applicable to the instant application, because the variants in Example 14 at least share 95% sequence identity with SEQ ID NO:3, and sharing the same well known function. In the instant application, the limitation of sharing 95% sequence identity, or a common structure, that correlates with the ability to elicit a T cell response, is not disclosed in the claims, or the specification.

Appellant argues that what the Examiner appears to require complete structure of an unspecified quantity of peptides with examples showing that they actually provoke T cell, which is not required as per the Enzo and Lilly cases. Appellant argues that the present claims require a specific function, i.e. the ability to be processed to a T cell epitope. Appellant argues that there is no evidence put forth by the Examiner that one would not be able to determine if a claimed molecule possessed these characteristics. Appellant argues that structurally the claims require a starting point, i.e. the amino acid sequence encoded by SEQ ID NO:1, coupled with the function of eliciting T cell response. Appellant argues that structure is correlated with function, by reference to what has been incorporated by reference. Appellant argues that the specification discloses three species with function, and how to determine what does and what does not function.

This is not found to be persuasive.

Appellant misrepresents the Examiner when citing the Examiner appears to require complete structure of an unspecified quantity of peptides with examples showing that they actually provoke T cell. Rather, the Examiner cited the standards as shown in the examples of Lilly and Enzo, requiring disclosure of either a representative number of species, or a common structure, which structure correlates with a disclosed function.

In the instant application, the claims and the specification clearly do not meet the standards as shown in the example of Enzo, because although the claims require a specific function, there is no correlation between structure and the function of eliciting T cell response, in view that no common structure is disclosed, which common structure is correlated with the function of eliciting T cell response, supra. The disclosure of the whole protein encoded by SEQ ID NO:1 is not a common structure, because the claimed immunoreactive portions encompasses any T cell epitopes of said protein, and because the structure of each T cell epitope is different and cannot be predicted, supra. Thus, the claims and the specification clearly do not meet the standards as shown in the example of Enzo.

Further, the claims and the specification do not meet the standards as shown in the example of Lilly, because the cited three peptides, SEQ ID NO:4, 5, 6, that elicit T cell response in the specification are not representative species, because they do not share a common structure with the claimed immunoreactive portions, which encompass any T cell epitopes of the protein encoded by SEQ ID NO:1, supra. Further, the cited peptides that are expected to bind to MHC molecules are not representative species, because one cannot predict whether these peptides have the function of eliciting T cell response, supra. Thus the claims and the specification do not meet the standards as shown in the example of Lilly. In view of the above, one would conclude that Appellant did not have possession of the claimed immunoreactive portions at the time the invention was made.

In addition, teaching how to screen for a peptide that has T cell response is not an adequate description of the structure of the claimed genus of immunoreactive peptides, supra. It is noted that "adequate written description requires more than a mere statement that it is part of

the invention and a reference to a potential method of isolating it. The nucleic acid itself is required". See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

For the reasons set forth above, the specification does not meet the 112, first paragraph written description requirement, and one of skill in the art would reasonably conclude that Appellant did not have possession of the claimed genus of immunoreactive portions at the time the invention was made.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

MINH-TAM DAVIS, PhD.

Patent Examiner

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SUPERVISORY PATENT EXAMINER

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